REMARKS

Claims 41-43, which have been withdrawn from consideration, have been cancelled without prejudice or disclaimer. The word "about" in claim 37 is removed in order to avoid the Examiner's interpretation that "an amount of about 50 mg/mL to about 400mg/mL" includes 20mg/mL of the antibody. Applicants specifically preserve the right to pursue the unamended claim in a continuing application. Claim 45 has been added which finds support in at least claim 37.

**Section 103(a)**

Claims 37-40 and 44 are rejected under 35 USC Section 103(a) as being unpatentable over US Patent No. 5,965,709 ("the '709 patent") in view of US Patent No. 5,580,856 ("the '856 patent").

As to the '856 patent, the Examiner urges that 'the upper limit is about 20mg/mL which meets the limitations of the instant claims "about 50mg/mL."'

Purely in the interests of expediting prosecution, and without acquiescing in the rejection, Applicants have amended claim 37 to remove the word "about" with respect to the 50mg/mL. Applicants believe that the amendment of claim 37 obviates the rejection, since the rejection presupposes that the claim includes 20mg/mL of the antibody in the formulation. Applicants submit that the '856 patent fails to disclose or suggest a reconstituted formulation comprising an antibody which binds IgE in an amount of about 50 mg/mL to about 400mg/mL , let alone therapy therewith as in claim 37. In the actual examples of the '856 patent, the concentration of the protein in the reconstituted formulation was much less than about 50mg/mL. In particular, starting protein concentrations in the examples were: 0.5 mg/mL KGF, 0.8 mg/mL IL-2 analog and 1.5 mg/mL RNase A (see column 8, lines 62-63 of the '856 patent). 1mL of the solution was lyophilized (see column 9, lines 1-19) and the lyophilized sample was reconstituted in 1mL of water or "additive solutions" (see column 9, lines 24-25). In other words, the protein concentration was decreased in the reconstituted formulation, because the volume of the reconstituted formulation must have been greater than that of the pre-lyophilized formulation. Even at the top of column 8 of the '856 patent where hypothetical protein concentrations in the reconstituted formulation are mentioned, the maximum protein concentration is only 20mg/mL. No stability data is provided for a formulation with a protein concentration of 20mg/mL, let alone a formulation as in the instant application wherein the anti-IgE antibody concentration in

the reconstituted formulation is about 50 mg/mL to about 400mg/mL. Clearly, the presently claimed invention is patentable over the cited art.

Reconsideration and withdrawal of the Section 103 rejection is respectfully requested in view of the above.

**IDS**

A copy of the missing references from the 1/24/01 IDS will be hand delivered to the PTO, along with a clean PTO 1449 form for the Examiner to initial. Applicants note that this is the second time these references are being hand delivered to the PTO.

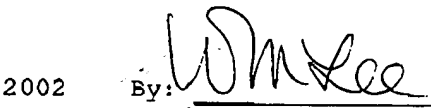
Applicants additionally point out that a Supplemental IDS (citing ref. nos. 209-290) was hand delivered to the former examiner - Examiner Jamroz - on 6/20/02. If the Supplemental IDS is not available, a further copy can be provided.

Applicants respectfully request that the Examiner initial the relevant PTO-1449 forms confirming consideration of all the cited art.

Applicants believe that this case is now in condition for allowance, and look forward to early receipt of same. However, if there are outstanding issues to be resolved, the Examiner is invited to call the undersigned to discuss same.

Respectfully submitted,
GENENTECH, INC.

Date: September 30, 2002

By: 

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

IN THE CLAIMS:

Please amend claim 37 as follows:

37. (Amended) A method for treating a mammal comprising administering a therapeutically effective amount of a stable reconstituted formulation to the mammal in order to treat a disorder selected from the group consisting of an IgE-mediated allergic disease, a parasitic infection, interstitial cystitis and asthma in the mammal, wherein the reconstituted formulation comprises an antibody which binds IgE in an amount of [about] 50 mg/mL to about 400mg/mL and has been prepared by reconstituting a lyophilized mixture of the antibody and a lyoprotectant in a diluent, wherein the antibody concentration in the reconstituted formulation is about 2-40 times greater than the antibody concentration in the mixture before lyophilization.

Please cancel claims 41-43, without prejudice or disclaimer.

Please add the following claim:

45. (New) A method for treating a mammal comprising administering a therapeutically effective amount of a formulation to the mammal in order to treat an IgE-mediated allergic disease in the mammal, wherein the formulation comprises an antibody which binds IgE in an amount of 50 mg/mL to about 400mg/mL.